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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,699	09/08/2000	Birgit Oppmann	DX01042X	3652

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DNAX RESEARCH INSTITUTE
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER	
DECLOUX, AMY M	
ART UNIT	PAPER NUMBER
1644	6

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/658,699	Oppmnn et al.
Examiner	**Art Unit**
D Cloux, Amy	1644

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-50 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-50 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Note: In the folowing groupings, claim 30 is considered to be intended to depend from claim 29, rather than claim 28.

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, drawn to a composition comprising a plurality of distinct segments of IL-12 p40 and a plurality of distinct segments of IL-B30, and a kit, classified in Class 514, subclass 2,

II. Claims 5-12, drawn to a nucleic acid, a cell comprising said nucleic acid, a kit comprising said nucleic acid, class 536, subclass 23.5, class 435, subclasses 6, 69.1, 320.1, and 252.3.

III. Claim 13, drawn to an antagonist of IL-12 p40/IL-B30, classified in Class 514, subclass 2,

IV. Claims 14-16 and 19 drawn to a binding compound comprising an antigen binding site, and a kit thereof, and a composition thereof, classified in Class 530, subclasses 387.1, 387.9, 388.23, 389.2 and class 424, subclasses 139.1, 145.1 and 158.1,

V. Claims 17-18, drawn to a method of producing an antigen:antibody complex, classified in Class 435, subclass 7.2,

VI. Claims 20-28, drawn to a method of modulating physiology or development of a cell or a tissue, comprising contacting said cell with a composition of claim 1, classified in Class 514, subclasses 15-16,

VII. Claim 20, drawn to a method of modulating physiology or development of a cell or a tissue, comprising contacting said cell with an antagonist of a composition of claim 1, classified in Class 424, subclass 184.1,

VIII. Claims 29-30, drawn to a method of increasing the secretion of IL-B30 or IL-12 p40, classified in Class 424, subclass 184.1,

IX. Claims 31-32, drawn to a method of screening for a receptor which binds the composition of claim 3, classified in Class 435, subclass 7.2,

X. Claims 33-49, drawn to a method of modulating the inflammatory response, comprising an agonist of mammalian IL-B30 protein, wherein said modulating is increasing the response, classified in Class 424, subclasses 145.1 and

158.1 and class 514, subclass 2,

XI. Claims 33-49, drawn to a method of modulating the inflammatory response, comprising an agonist of mammalian IL-B30 protein, wherein said modulating is decreasing the response, classified in Class 424, subclasses 145.1 and 158.1 and class 514, subclass 2,

XII. Claims 33-40, drawn to a method of modulating the inflammatory response, comprising an antagonist of mammalian IL-B30 protein, wherein said modulating is increasing the response, classified in Class 424, subclasses 145.1 and 158.1 and class 514, subclass 2,

XIII. Claims 33-40, drawn to a method of modulating the inflammatory response, comprising an antagonist of mammalian IL-B30 protein, wherein said modulating is decreasing the response, classified in Class 424, subclasses 145.1 and 158.1 and class 514, subclass 2,

XIV. Claim 50, drawn to a method of inducing proliferation of memory T-cells by administering IL-B30 or an agonist thereof , classified in class 514, subclass 2.

Note: each claim will be examined only to the extent of the elected invention, ie Claims 20 and 33-49.
Note: For examination purposes, claim 30 is being interpreted as depending on claim 29. Applicant is requested to clarify.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IV are unique products. They differ with respect to their physicochemical properties and are therefore patentably distinct.

3. Groups V-XIV are unique methods. Groups V, VI/VII, VII, IX, X/XI/XII/XIII and XIV differ with respect to their respective endpoints. Groups VI and VII have the same endpoint but differ with respect to ingredients. Groups X, XI, XII, and XIII have the same endpoint but differ with respect to ingredients. Therefore, Groups V-IX are patentably distinct each from the other.

4A. Groups I and VI-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the composition comprising a plurality of distinct segments of IL-12 p40 and a plurality of distinct segments of IL-B30, can be as in affinity purification methods, as well as in to a method of modulating physiology or development of a cell or a tissue, or in a method of increasing the secretion of IL-B30 or IL-12 p40, or in a method of screening for a receptor which binds the composition of claim 3, or a method of producing an antigen:antibody complex.

4B. Groups IV andV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, a binding compound comprising an antigen binding site, can be in affinity purification methods, as well as in a method of producing an antigen:antibody complex.

5. Because these inventions I-XIV are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of the non patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

6. If groups I, IV, V, VI or VII is elected, the applicant is further required under 35 U.S.C. 121,

To elect a composition comprising a distinct number of distinct segments of IL-12 p40, or a method comprising said specific composition,

To elect a composition comprising a distinct number of distinct segments of IL-B30, or a method comprising said specific composition,

To elect a composition comprising a distinct number of consecutive amino acids making up each segment of IL-12 p40, or a method comprising said specific composition,

To elect a composition comprising a distinct number of consecutive amino acids making up each segment of IL-B30, or a method comprising said specific composition.

7. If groups I or II is elected, the applicant is further required under 35 U.S.C. 121,

To elect a composition comprising a nucleic acid encoding a distinct number of distinct segments of IL-12 p40,

To elect a composition comprising a nucleic acid encoding a distinct number of distinct segments of IL-B30,

To elect a composition comprising a nucleic acid encoding a distinct number of consecutive amino acids making up each segment of IL-12 p40,

To elect a composition comprising a nucleic acid encoding a distinct number of consecutive amino acids making up each segment of IL-B30,

7. If group I is elected, the applicant is further required to elect a composition comprising another specific entity such as IL-18, to be combined with as recited in part D of Claim 3.

8. If group II is elected, the applicant is further required

to elect a nucleic acid obtained with specific wash conditions, such as those recited in claim 11,

to elect a nucleic acid obtained with a stretch of a specific number of nucleotides for both IL-12 p40 or IL-B30, such as recited in claims 11 or 12,

9. If group III is elected, the applicant is further required to elect a specific entity with which the antagonist is combined such as IL-1 or a specific steroid, as recited in claim 13.

10. If group VI is elected the applicant is further required to elect
a method comprising a specific TH1 response as recited in claim 23,
a method comprising a specific contacting agent, such as one recited in claim 25.

11. If group IX is elected the applicant is further required to elect
a method comprising a specific composition of claim 3,
a method comprising a specific TH1 response as recited in claim 23,
a method comprising a specific contacting agent, such as one recited in claim 25.

12. If group X-XIII is elected, applicant is further required:
to elect a method comprising a specific ILB30 protein,
to elect a specific antagonist such as ant antibody as recited in claim 34,
to elect a method wherein the sign or symptom of an acute phase inflammatory response is found in a specific tissue such as one of the tissues recited in claim 36,
to elect a method wherein said modulating effect has an effect on a specific molecule such as IgA as recited in claim 39.

13. If group X or XI is elected, applicant is further required
to elect a method wherein said administering is in combination with a specific compound, such as any one of the components recited in claim 47 such as an antagonist of a antiinflammatory cytokine or an agonist of a antiinflammatory cytokine.

14. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the

elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

17. Claims 1-50 are generic.

18. The species are distinct each from the other because the encompassed products differ with respect to their physicochemical properties, and the encompasses hybridization steps comprise distinct method steps, and therefore each of the species is patentably distinct.

19. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner

Group 1640
Technology Center 1600
December 11, 2001

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644